

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 21, 2017

Jayne Walz Regulatory Manager Valent BioSciences LLC 870 Technology Way Libertyville, IL 60048

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – To Revise

the Expiration Date Statement on the Label and Make Revisions Requested by the EPA Response to the Storage Stability and Corrosion Characteristics Term of Registration Product Name: Foray 2WG Biological Insecticide (Water Dispersible Granules)

EPA Registration Number: 73049-481 Application Date: January 6, 2017 OPP Decision Number: 525281

Dear Ms. Walz:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration

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process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

Additionally, as requested by the EPA in a letter dated June 12, 2015, you have replaced "Expiration Date:" with "Not for sale or use after [Date stamped/placed on labeling will be 12 months after the date of manufacture]" on the label. Thus, you have fulfilled term #4 of the September 27, 2012, Foray 2WG Biological Insecticide (Water Dispersible Granules) Registration Notice.

If you have any questions, please contact Daniel Schoeff by phone at (703) 347-0143 or via email at schoeff.daniel@epa.gov.

Sincerely,

Jeannine Kausch, Product Manager 92 Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

Foray® 2WG

Biological Insecticide (Water Dispersible Granules)

A	IVI	\mathbb{R}	IN	GR	10	DI	EN	\mathbf{T}_{2}

Bacillus thuringiensis subsp. kurstaki, strain VBTS-2546 fermentation	n solids,
spores and insecticidal toxins*	67.0%
Other Ingredients	33.0%
TOTAL	100.0%

*Potency: 110,000 Cabbage Looper Units (CLU)/mg of product (equivalent to 50 billion CLU per pound of product).

The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

KEEP OUT OF REACH OF CHILDREN CAUTION

Manufactured for: Valent BioSciences LLC 870 Technology Way Libertyville, IL 60048

EPA Reg. No. 73049-481 EPA Est. No. ACCEPTED

08/21/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

73049-481

Lot	No:	
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Net Weight:

Not for sale or use after [Date stamped/placed on labeling will be 12 months after the date of manufacture]

FIRST AID				
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. 			
	 Call a poison control center or doctor for treatment advice. 			
	HOTLINE NUMBER			
doctor, or go	duct container or label with you when calling a poison control center or ing for treatment. You may also contact 1-800-892-0099 (24 hours) for nedical treatment and/or transport emergency information. For all other			
information, call 1-800-6-Valent.				

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- o Long-sleeved shirt and long pants
- Waterproof gloves
- o Shoes plus socks

Mixers/loaders and applicators must wear a NIOSH-approved particulate respirator with any R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

User Safety Recommendations

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

User should remove PPE immediately after handling the product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses, except when applying aerially over the forest canopy: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

This product must not be applied aerially within ¼ mile of any habitats of endangered or threatened Lepidoptera species. No manual application can be made within 300 feet of any threatened or endangered Lepidoptera species.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not apply this product in a way that will contact workers or their persons, either directly or through drift. Only protected handlers may be in the area during application.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water) is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of the treated areas until sprays have dried.

PRODUCT INFORMATION

Foray 2WG Biological Insecticide Water Dispersible Granules (hereafter referred to as Foray 2WG) is a biological insecticide for the control of lepidopterous larvae. It contains the spores and endotoxin crystals of *Bacillus thuringiensis kurstaki*. Foray 2WG must be ingested by the larvae to be effective. Susceptible larvae that ingest Foray 2WG cease feeding within a few hours and die within 2-5 days.

Foray 2WG can be mixed with water at a central location where a good, clean water source and appropriate mixing equipment are available and transported to the use location.

USE RESTRICTIONS

Not for use on trees grown for food.

APPLICATION INSTRUCTIONS

Do not apply this product through any type of irrigation system.

Use aerial or ground equipment to apply Foray 2WG. Mix Foray 2WG with quantities of water sufficient to provide thorough coverage to protect deciduous or coniferous trees. The amount of water needed per acre will depend upon plant size, density, forest canopy, spray equipment, and local experience. Use rotary or other atomizers to provide droplet Volume Median Diameters (VMD) of 60-100 microns for needle conifers and 50-150 microns for deciduous hardwoods.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many spray equipment- and weather-related factors determines the potential for spray drift. The applicator and the treatment coordinator are responsible for considering all of these factors when making decisions.

Crop	Pests	Rate ¹	Dosage ¹	
		(oz Foray 2WG/A)	(Billion CLU/A)	
Forests	Gypsy Moth	2.6 - 12.8	8 - 40	
Shade Trees	Elm Spanworm			
Ornamental Trees	Spruce Budworm	2.6 - 9.6	8 - 30	
Ornamental Sugar	Browntail Moth			
Maple Trees	Douglas Fir			
Ornamental Fruit,	Tussock Moth			
Nut & Citrus Trees	Coneworm			
	Buck Moth			
	Tussock Moth	1.9 - 5.2	6 - 16	
	Pine Butterfly			
	Bagworm			
	Leafroller			
	Tortrix			
	Mimosa Webworm			
	Tent Caterpillar			
	Blackheaded Budworm			
	Saddled Prominent			
	Caterpillar			
	Saddleback Caterpillar			
	Eastern & Western			
	Hemlock Looper			
	Orangestriped Oakworm			
	Satin Moth			
	Redhumped Caterpillar	1.3 - 2.6	4 - 8	
	Spring & Fall Cankerworm			
	California Oakworm			
	Fall Webworm			

Special Instructions

MIXING

Foray 2WG is designed to be mixed with water as a suspension in a mix tank having the capability of mechanical or hydraulic agitation (in-tank or over-the-top circulation).

Use a mixing tank size capable of producing moderate to high circulation of the mix to assure complete suspension of Foray 2WG in the water.

Begin by filling the tank with 50–75% of the desired spray volume of water. Start the mechanical or hydraulic agitation of the water to provide moderate to high circulation. Slowly add the required amount of Foray 2WG and then the remaining volume of water. If foaming of the mix occurs during the mixing operation, reduce circulation and/or add a compatible anti-foaming agent. Continue the agitation until all Foray 2WG is suspended.

¹Use the highest rates on advanced larval stages or under high density larval populations.

Agitate as necessary to maintain suspension. After mixing with water, the product must be used within 72 hours.

The use of a spreader-sticker is not required for Foray 2WG. If interested in using commonly used spray-tank adjuvants, it is advisable to test the physical compatibility in a smaller container in proportionate quantities; consult with the adjuvant manufacturer for further information.

Ground and Aerial Application:

Use amount of Foray 2WG in ground and aerial equipment with quantities of water sufficient for adequate mixing and spray deposition. The amount of water needed per acre will depend upon plant size, weather conditions, spray equipment used and local experience. Consult with product manufacturer for further information.

AGRICULTURAL USE INSTRUCTIONS

Use sites: forestry and ornamental trees grown in nursery and greenhouses.

Monitor treatment areas to detect early infestations.

Apply Foray 2WG when eggs have completed hatching and larvae are small (early instars) and before significant defoliation occurs. Larvae must be actively feeding to be affected.

Repeat applications when high larval populations or extended egg hatch is present. Schedule second application 5-7 days after the first one to maintain control and protect new plant (tree) growth. Factors affecting spray interval include rate of plant growth, weather conditions, and reinfestations. Monitor pest populations and foliage development to determine proper timing of applications. Under conditions of heavy pest pressures or when large larvae are present, use the highest rate allowed, shorten the application interval, and/or improve spray coverage to enhance control. Thorough coverage is essential.

NON-AGRICULTURAL USE INSTRUCTIONS

For use on plants intended only for aesthetic purposes or climatic modification and being grown in interior plantscapes, in ornamental gardens or parks, on golf courses, or on private or public lawns and grounds or for wide-area public pest control programs sponsored by government entities, such as gypsy moth control.

Monitor treatment areas to detect early infestations.

Apply Foray 2WG when eggs have completed hatching and larvae are small (early instars) and before significant defoliation occurs. Larvae must be actively feeding to be affected.

Repeat applications when high larval populations or extended egg hatch is present. Schedule second application 5-7 days after the first one to maintain control and protect new plant (tree) growth. Factors affecting spray interval include rate of plant growth, weather conditions, and reinfestations. Monitor pest populations and foliage development to determine proper timing of applications. Under conditions of heavy pest pressures or when large larvae are present, use the highest rate allowed, shorten the application interval, and/or improve spray coverage to enhance control. Thorough coverage is essential.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep containers tightly closed when not in use. Do not store at temperatures greater than 100°F.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling:

Rigid, Plastic Containers (50pounds or less): Nonrefillable container. Do not reuse or refill this container.

Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ½ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of the container in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

Rigid, Plastic Containers (Greater than 50 pounds): Nonrefillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

<u>Triple rinse as follows</u>: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of the container in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

<u>Pressure rinse as follows</u>: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Then offer for recycling if available or puncture and dispose of the container in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

Non-rigid, Plastic Containers: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

WARRANTY AND DISCLAIMER To the extent consistent with applicable law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. To the extent consistent with applicable law, user assumes all risk of use, storage or handling not in accordance with accompanying directions.

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